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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/038,520 | 10/22/2001 | Kenneth J. Livak | 4340C2 | 6592 |

22896 7590 11/26/2003

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APPLIED BIOSYSTEMS
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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 11/26/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,520

Applicant(s)

LIVAK ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action and amendment (Paper-No. 10) filed on August 4, 2003 has been entered and considered.
2. Receipt of the property rights statement (Paper No. 12) is acknowledged and entered.
3. Claims 1-32 are cancelled, and new claims 33-50 are added by the instant amendment (Paper No. 10). Claims 33-50 are currently pending in this application.

Response to arguments

4. Applicants' arguments and amendment have been fully considered and found persuasive in part.
5. With reference to the rejection made in the previous office action under 35 USC 112 second paragraph, the rejection is withdrawn in view of the amendment (Paper No. 10).
6. Applicant's arguments with respect to the rejection under statutory double with US. Patent 6,309,829 to the claims 1-32 have been considered and the rejection is withdrawn in view of the amendment.
7. Applicant's arguments with respect to the rejection under nonstatutory obviousness type double patenting with US. Patent 5,945,284 to the claims 1-32 have been considered and the rejection is withdrawn in view of the amendment. However, the new claims meet the criteria for nonstatutory obviousness type double-patenting and hence the rejection is re written below including the new limitations.

New Grounds of rejections necessitated by Amendment

NonStatutory Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or

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improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claims 33-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,945,284. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a method for determining the number of repeat unite in a repeat region of a target nucleic acid and the method comprises (a) annealing a primer-complementary protion to a target nucleic acid thereby forming a target-primer hybrid; (b-e) performing a first primer extension, separating the target-primer hybrid from the first primer extension reagent and performing a second primer extension , wherein at least first or second primer extension reagent includes labeled extendible nucleotide and separating target-primer hybrid from second primer extension reagent (f-h) measuring a signal produced by the label, treating the label so as to render the label undetectable and repeating the steps a through g until the signal is substantially less than a signal detected in a previous cycle and (i) determining the number of repeat unit in the said target nucleic acid. The patented claims encompass said method and the only variation being in the recitation of said method. The instant claims vary in step b in reciting 'wherein the first primer extension reagent allows said first primer extension reaction to proceed only to the extent that said primer is extended by an amount less than a full repeat. However, an additional

explanation of the step b would have been obvious to one having ordinary skill in the art at the time the invention was made because second primer extension clearly indicates that the first primer extension is not complete. Therefore it is an obviousness type of double patenting.

B. Claims 33-50 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,309,829. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a method for determining the number of repeat unit in a repeat region of a target nucleic acid and the method comprises (a) annealing a primer-complementary portion to a target nucleic acid thereby forming a target-primer hybrid; (b-e) performing a first primer extension, separating the target-primer hybrid from the first primer extension reagent and performing a second primer extension, wherein at least first or second primer extension reagent includes labeled extendible nucleotide and separating target-primer hybrid from second primer extension reagent (f-h) measuring a signal produced by the label, treating the label so as to render the label undetectable and repeating the steps a through g until the signal is substantially less than a signal detected in a previous cycle and (i) determining the number of repeat unit in the said target nucleic acid. The patented claims encompass said method as genus encompassing a species because the patented claims disclose said method with plurality of different primers with a polynucleotide sample to form one or more target-primer hybrid(s), variation being in the recitation of plurality of primers. Further the instant claims vary in step b in reciting 'wherein the first primer extension reagent allows said first primer extension reaction to proceed only to the extent that said primer is extended by an amount less than a full repeat. However, However, extension of the patented claim method to one target-primer hybrid formation and an additional

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explanation of the step b in the instant claims would have been obvious to one having ordinary skill in the art at the time the invention was made because narrowing the instant claims from a broader scope is an obvious variation and second primer extension clearly indicates that the first primer extension is not complete. Therefore it is an obviousness type of double patenting.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 703-308-1119. The fax phone numbers for the organization

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where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Suryaprabha Chunduru
November 24, 2003


JEFFREY FREDMAN
PRIMARY EXAMINER